IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

RUBY CAVEECK,	)	**Civil Action No.:**
	)	
Plaintiff,	)	
	)	
v.	)	**JURY TRIAL DEMANDED**
	)	
	)	
JOHNSON & JOHNSON and ETHICON, INC.,	)	
	)	
	)	
Defendants.	)	
	)	
	)	
	)	

COMPLAINT AND JURY DEMAND

Come now Plaintiff, Ruby Caveeck, by and through undersigned counsel, brings this action against Defendants Johnson & Johnson and Ethicon, Inc. (hereinafter "Defendants"), and allege as follows:

Parties

1. Plaintiff is, and was, at all relevant times, a citizen and resident of Pennsylvania and the United States.

2. Defendant Johnson & Johnson ("J&J") is a corporation incorporated in New Jersey, and according to its website, the world's largest and most diverse medical device and diagnostics company, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

3. Defendant J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its products, including but not limited to its hernia repair mesh products. Within J&J

there are three sectors: medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution and sale of the hernia repair mesh products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Ethicon Inc.

4. Defendant Ethicon, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson. Defendant Ethicon, Inc. is a corporation incorporated in the State of New Jersey with its principal place of business in Somerville, New Jersey.

5. Ethicon is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including Proceed (hereinafter may be referred to as the "product").

6. J&J, directly and/or through the actions of Ethicon, Inc., has at all pertinent times been responsible for the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of Proceed.

7. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its defective mesh products at issue in the instant action, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

8. Defendants are vicariously liable for the acts and/or omissions of its employees and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

Jurisdiction and Venue

9. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiff and all Defendants. The amount in controversy exceeds $75,000.

10. This Court has personal jurisdiction over each of the Defendants pursuant to the Pennsylvania Long-Arm Statute, 42 Pa.C.S.A. § 5322. Defendants transact business within the State of Pennsylvania, contracted to sell and supply their Proceed products in the State of Pennsylvania, and committed tortious acts and omissions in Pennsylvania. Defendants' tortious acts and omissions caused injury to Plaintiff in the State of Pennsylvania. Defendants employ sales representatives in the State of Pennsylvania to sell their Proceed products throughout the State, including the Proceed implanted in Plaintiff. Defendants have purposefully engaged in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, medical devices including Proceed products in Pennsylvania, for which they derived significant and regular income. The Defendants intended and reasonably expected that that their defective mesh products, including Proceed, would be sold and implanted in Pennsylvania and could cause injury in Pennsylvania.

11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2).

Facts Common To All Counts

12. On or about November 16, 2005, Plaintiff underwent surgery at UPMC McKeesport, 1500 5th Ave., McKeesport, PA 15132, for a recurrent left incisional ventral hernia repair by Dr. Lang. During the procedure, Dr. Lang implanted a Proceed Surgical Mesh into Plaintiff.

13. On or about August 18, 2015, Plaintiff returned to UPMC McKeesport a recurrent incisional hernia repair, which necessitated a two-step procedure. Part one of the procedure was to remove the Defendant's mesh and was performed by Dr. Marc Cordero. During the procedure, Dr. Cordero noted dense adhesions were encountered and the Plaintiff's bowel was fused to the previously placed mesh. Dr. Cordero spent nearly 2 hours during the surgery attempting to free the Plaintiff's bowel from the Defendant's mesh with sharp dissection. During the dissection, Plaintiff's bowel was perforated and had to be resected. Dr. Cordero noted that the bowel perforation "was both inherent and unavoidable to the procedure."

14. Part two of Plaintiff's August 18, 2015, hernia repair was performed by Dr. Sandeep Kathju, a plastic surgeon. Dr. Kathju noted "the patient had significant scarring all throughout her subcutaneous tissues in the abdominal wall…"

15. Defendants manufactured, sold, and/or distributed the Proceed device to Plaintiff, through her doctors, to be used for treatment of hernia repair.

16. Plaintiff was discharged from UPMC McKeesport on or about August 28, 2015.

17. Plaintiff was readmitted to UPMC McKeesport on or about September 2, 2015, with a small bowel obstruction.

18. On or about September 11, 2015, Plaintiff was transferred to the transitional care unit and underwent daily physical and occupational therapy, because Plaintiff could no longer ambulate on her own.

19. On or about September 15, 2015, Plaintiff was discharged from UPMC McKeesport.

20. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of Proceed, including providing the warnings and instructions concerning the product.

21. Among the intended purposes for which Defendants designed, manufactured and sold Proceed was use by surgeons for hernia repair surgeries, the purpose for which the Proceed was implanted in Plaintiff.

22. Defendants represented to Plaintiff and Plaintiff's physicians that Proceed was a safe and effective product for hernia repair.

23. Defendants' Proceed was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the Proceed, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; inadequate or failure of incorporation/ingrowth; migration; scarification; deformation of mesh; improper wound healing; excessive and chronic inflammation; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tissue damage and/or death; and other complications.

24. Proceed has a unique design incorporating a layer of oxidized regenerated cellulose (ORC) over a layer of polydioxanone, which in turn coats a polypropylene mesh. This design is not used in any other hernia repair product sold in the United States. The multi-layer coating was represented and promoted by the Defendants to prevent or minimize adhesion and inflammation and to facilitate incorporation of the mesh into the body, but it did not. Instead, the multi-layer coating prevented adequate incorporation of the mesh into the body and caused or contributed to an intense inflammatory and chronic foreign body response resulting in an adverse tissue reaction including migration and damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper healing.

25. The ORC layer of the Proceed has a tendency to delaminate from the other layers of the mesh, resulting in air pocket, which leads to the formation of a seroma as the body fills the air pocket with fluid. Seroma formation increases the risk of infection, abscess formation and other complications.

26. When affixed to the body's tissue, the impermeable multi-layer coating of the Proceed prevents fluid escape, which leads to seroma formation, and which in turn can cause infection, abscess formation and other complications.

27. The multi-layer coating provides a breeding ground for bacteria in which the bacteria cannot be eliminated by the body's immune response, which allows infection to proliferate.

28. The multi-layer coating of Defendants' Proceed is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

29. Defendants knew or should have known of the cytotoxic and immunogenic properties of the multi-layer coating of the Proceed prior to introducing it into the stream of commerce.

30. When the multi-layer coating of the Proceed is disrupted, delaminates, and/or degrades, the "naked" polypropylene mesh is exposed to the adjoining tissue and viscera, and can become adhered to organs, cause damage to organs, and potentiate fistula formation.

31. These manufacturing and design defects associated with the Proceed were directly and proximately related to the injuries suffered by Plaintiff.

32. Neither Plaintiff nor her implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of Proceed. Moreover, neither Plaintiff nor her implanting physician were adequately warned or informed by Defendants of the risks associated with the Proceed or the frequency, severity, or duration of such risks.

33. The Proceed implanted in Plaintiff failed to reasonably perform as intended. The mesh caused serious injury and had to be surgically removed via invasive surgery, and necessitated additional invasive surgery to repair the hernia that the Proceed was initially implanted to treat.

34. Plaintiff's severe adverse reaction, and the necessity for surgical removal of the Proceed, directly and proximately resulted from the defective and dangerous condition of the product and Defendants' defective and inadequate warnings about the risks associated with the product, and the frequency, severity and duration of such risks. Plaintiff has suffered, and will continue to suffer, both physical injury and pain and mental anguish, permanent and severe scarring and disfigurement, lost wages and earning capacity, and has incurred substantial medical

bills and other expenses, resulting from the defective and dangerous condition of the product and from Defendants' defective and inadequate warnings about the risks associated with the product.

COUNT I
Strict Product Liability: Defective Manufacture

35. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

36. Defendants expected and intended the Proceed product to reach users such as Plaintiff in the condition in which the product was sold.

37. The implantation of Proceed in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

38. At the time the Proceed that was implanted in Plaintiff's body, the product was defectively manufactured.

39. Defendants' manufacturing and quality control/assurance non-compliance resulted in the non-conformance of the Proceed implanted in Plaintiff with intended manufacturing and design specifications.

40. The multi-layer coating of the Proceed also failed to conform to the Defendants' specifications in terms of shelf-life, thickness, durability, and quality.

41. Upon information and belief, Defendants' utilized adulterated polypropylene to manufacture Proceed.

42. Upon information and belief, Defendants' utilized adulterated cellulose to manufacture the Proceed.

43. As a direct and proximate result of the defective manufacture of the Proceed, Plaintiff suffered injuries and damages as summarized herein.

COUNT II
Strict Product Liability: Defective Design

44. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

45. At the time the Proceed that was implanted in Plaintiff's body, the product was defectively designed. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

46. Defendants expected and intended the Proceed product to reach users such as Plaintiff in the condition in which the product was sold.

47. The implantation of Proceed in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

48. The risks of the Proceed significantly outweigh any benefits that Defendants contend could be associated with the product. The multi-layer coating, which is not used in any other hernia mesh product sold in the United States, prevents tissue from incorporating into the mesh, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection. The impermeable multi-layer coating leads to seroma formation, and provides a breeding ground for infection, and protects bacteria from being eliminated by the body's natural immune response.

49. The multi-layer coating of the Proceed, which was marketed, promoted and intended as a barrier against adhesion to the internal organs, was only temporary; it was expected and intended to degrade over time inside the body. Thus, this coating prevented tissue ingrowth in the short term, and degraded in the long-term, eventually leaving the "naked" polypropylene mesh exposed to the internal viscera and tissues. The degradation of this multi-layer coating caused or exacerbated an intense inflammatory and foreign body reaction. Once exposed to the viscera, the polypropylene mesh will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the multi-layer coating (to prevent adhesion to the internal viscera and organs) was non-existent; the product provided no benefit while substantially increasing the risks to the patient.

50. The polypropylene mesh within the defective multi-layer coating of the Proceed was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the Proceed. When implanted adjacent to the intestines and other internal organs, as Defendants intended for Proceed, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

51. Proceed is sterilized with gamma irradiation, which oxidizes the cellulose, creating oxidized regenerated cellulose (ORC). Cellulose is not bioresorbable in humans until it has undergone oxidation. The complex oxidation process often results in non-homogenous materials, parts of which are unable to be resorbed.

52. Proceed is the only polypropylene hernia mesh currently on the market to utilize gamma irradiation for sterilization of the entire hernia mesh. Gamma irradiation causes polypropylene to significantly degrade, and the degradation continues for a long time after the

actual sterilization event. Gamma irradiation induced polypropylene degradation results in severe embrittlement of the polypropylene.

53. The ORC layer of Proceed is compromised in the presence of blood or where there is prolonged fibrin deposition due to inflammation. Fibrin is able to readily penetrate ORC and gain access to the base polypropylene. It is this fibrin bridging which initiates adhesion formation. The polypropylene component of Proceed incites a chronic inflammatory response, leading to prolonged fibrin deposition.

54. The appropriate treatment for complications associated with Proceed involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to the patient.

55. Proceed was designed and intended for intraperitoneal implantation, which involved the product being implanted in contact with the intestines and/or other internal organs, which unnecessarily increased the risks of adhesion, erosion, fistula formation, and other injuries.

56. At the time the Proceed was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products that would have prevented the injuries she suffered.

57. The Proceed product cost significantly more than competitive products because of its unique multi-layer coating, even though the multi-layer coating provided no benefit to consumers, and increased the risks to patients implanted with these devices.

58. The Proceed implanted in Plaintiff failed to reasonably perform as intended, and had to be surgically removed necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus provided no benefit to him.

59. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff suffered injuries and damages as summarized herein.

COUNT III
Strict Product Liability: Failure to Warn

60. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

61. At the time the Proceed that was implanted in Plaintiff's body, the warnings and instructions provided by Defendants for the Proceed were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

62. Defendants expected and intended the Proceed product to reach users such as Plaintiff in the condition in which the product was sold.

63. Plaintiff and her physicians were unaware of the defects and dangers of Proceed, and were unaware of the frequency, severity and duration of the defects and risks associated with the Proceed.

64. The Defendants' Instructions for Use provided with the Proceed expressly understates and misstates the risks known to be associated specifically with the Proceed by stating that "Potential adverse reactions are those typically associated with surgically implantable materials." No other surgical mesh sold in the United States – and no other "surgically implantable material" – suffers the same serious design flaws as Proceed. No other device or material contains the dangerous and defective multi-layer coating, which itself causes or

increases the risks of numerous complications, including prevention of incorporation, increased risk of seroma formation, immunologic response, increased risk for infection, and increased inflammatory reaction and foreign body response. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Proceed.

65. The Defendants' Instructions for Use for the Proceed failed to adequately warn Plaintiff's physicians of numerous risks which Defendants knew or should have known were associated with the Proceed, including the risks of the product's inhibition of tissue incorporation, pain, immunologic response, dehiscence, encapsulation, rejection, migration, scarification, shrinkage/contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, bowel obstruction, failure of repair/hernia recurrence, or hernia incarceration or strangulation.

66. Defendants failed to adequately train or warn Plaintiff or her physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.

67. Defendants failed to adequately warn Plaintiff or her physicians that the necessary surgical removal of the Proceed in the event of complications would leave the hernia unrepaired, and would necessitate further medical treatment to attempt to repair the same hernia that the failed Proceed was intended to treat.

68. Defendants represented to physicians, including Plaintiff's physician, that the multi-layer coating would prevent or reduce adhesion, and expressly intended for the Proceed to be implanted in contact with the intestines and internal organs and marketed and promoted the product for said purpose. Defendants failed to warn physicians that the Proceed prevented

adequate parietal tissue ingrowth, which is the desired biologic response to an implantable mesh device. Defendants failed to warn physicians that the multi-layer coating was only temporary and therefore at best would provide only a temporary adhesion barrier, and when the coating inevitably degraded, the exposed polypropylene would become adhered to the organs or tissue.

69. With respect to the complications that were listed in the Defendants' warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with Proceed were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.

70. If Plaintiff and/or her physicians had been properly warned of the defects and dangers of Proceed, and of the frequency, severity and duration of the risks associated with the Proceed, Plaintiff would not have consented to allow the Proceed to be implanted in her body, and Plaintiff physicians would not have implanted the Proceed in Plaintiff.

71. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized herein.

COUNT IV
Negligence

72. Plaintiff incorporates herein by reference the allegations in all prior Paragraphs as if fully set forth herein.

73. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for Proceed, but failed to do so.

74. Defendants knew, or in the exercise of reasonable care should have known, that Proceed was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom Proceed was implanted. Defendants knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in the Proceed.

75. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for Proceed, Plaintiff suffered injuries and damages as summarized herein.

COUNT V
Consumer Protection

108. Plaintiff incorporates all paragraphs of this Complaint as if set forth herein.

109. Defendants violated Pennsylvania's Consumer Protection Act, 73 P.S. § 201-1, *et seq.*, and/or any applicable consumer protection statute, by engaging in deceptive and/or unconscionable acts and practices.

110. As a direct and proximate result of the foregoing conduct by Defendants, Plaintiff was caused to be exposed to Defendants' defective products, thereby causing Plaintiff significant pain and suffering, mental anguish, and related medical costs and other damages as set forth herein.

COUNT VI
Breach of Express Warranty

76. Plaintiff incorporates herein by reference the allegations in all prior Paragraphs as if fully set forth herein.

77. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce Proceed.

78. In advertising, marketing and otherwise promoting Proceed to physicians, hospitals and other healthcare providers, Defendants expressly warranted that their Proceed was safe for use. In advertising, marketing and otherwise promoting Proceed, Defendants intended that physicians, hospitals and other healthcare providers rely upon their representations in an effort to induce them to use Proceed for their patients.

79. The Plaintiff was a person whom the Defendants could reasonably have expected to use, consume, or be affected by the Defendants' hernia mesh products as the Defendants specifically designed the Proceed for permanent implantation in patients exhibiting hernia such as Plaintiff.

80. With respect to Plaintiff, Defendants intended that Proceed be implanted in Plaintiff by her treating surgeon in the reasonable and foreseeable manner in which it was implanted and in accordance with the instructions for use and product specifications provided by Defendants. Plaintiff was in privity with Defendants.

81. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public including Plaintiff that Proceed was safe and fit for use by consumers including Plaintiff, that it was of merchantable quality, that its risks, side effects and potential complications are minimal and are comparable to other hernia mesh products, that it was adequately researched and tested and was fit for its intended use. Plaintiff and her physicians and healthcare providers relied upon these express representations and warranties made by Defendants and consequently, Plaintiff was implanted with Defendants' Proceed.

82. Defendants breached express representations and warranties made to Plaintiff and her physicians and healthcare providers with respect to the Proceed implanted in Plaintiff including the following particulars:

A. Defendants represented to Plaintiff and her physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' Proceed was safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Proceed;

B. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Proceed was as safe and/or safer than other alternative procedures and devices then on the market, meanwhile Defendants fraudulently concealed information that demonstrated that Proceed was not safer than alternative therapies and products available on the market; and

C. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Proceed was more efficacious than other alternative procedures, therapies and/or devices. Meanwhile Defendants fraudulently concealed information, regarding the true efficacy of Proceed.

83. At the time of making such express warranties, Defendants knew or should have known that Defendants' Proceed does not conform to the express warranties and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety.

84. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but

not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

COUNT VII
Breach of Implied Warranties of Merchantability

1. Plaintiff incorporates herein by reference the allegations in all prior Paragraphs as if fully set forth herein.

2. Defendants breached implied warranties with respect to the Proceed including the following particulars:

A. Defendants represented to Plaintiff and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Proceed was of merchantable quality and safe when used for its intended purpose meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Proceed;

B. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Proceed was safe, as safe as and/or safer than other alternative procedures and devices, meanwhile Defendants fraudulently concealed information, which demonstrated that the Proceed was not safe, as safe as or safer than alternatives and other products available on the market; and

C. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Proceed were more efficacious than other alternative

procedures and/or devices. Meanwhile Defendants fraudulently concealed information, regarding the true efficacy of Proceed.

3. In reliance upon Defendants' implied warranty, Plaintiff's implanting surgeon used Proceed to treat Plaintiff in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants and in accordance with the instructions for use and product specification provided by Defendants.

4. Defendants breached their implied warranty to Plaintiff in that the Defendants' Proceed was not of merchantable quality, safe and fit for its intended use nor was it adequately tested prior to being placed in the stream of commerce.

5. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice and with gross negligence, and evidenced reckless disregard and indifference to Plaintiff's rights, health and safety.

6. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

Count VIII
Punitive Damages

7. Plaintiff incorporates herein by reference the allegations in all prior paragraphs as if fully set forth herein.

8. Defendants failed to adequately test and study the Proceed to determine and ensure that the product was safe and effective prior to releasing the product for sale for permanent human implantation, and Defendants continued to manufacture and sell the Proceed after obtaining knowledge and information that the product was defective and unreasonably unsafe. Even though Defendants manufacture other hernia mesh devices that do not present the same risks as the Proceed, Defendants developed, designed and sold the Proceed, and continue to do so, because the Proceed has a significantly higher profit margin than other hernia repair products.

9. Defendants possessed knowledge that Plaintiff and Plaintiff's implanting physician were unaware of and did not have access to, such as the actual effectiveness, safety, complications, and rate of complications associated with the Proceed. Defendants intentionally withheld and actively concealed this information from the Plaintiff, the Plaintiff's implanting physician, and the entire medical community at large.

10. Defendants issued limited recalls on the Proceed to give the perception that the complications related to the Proceed were isolated problems that had been fixed.

11. Defendants never made changes to the Proceed to make it a safer product after issuing recalls on the Proceed

12. Defendant's actions and inactions demonstrate outrageous and egregious conduct done in a reckless disregard of the safety of its end users.

WHEREFORE, as a result of the acts and omissions and conduct of Defendants set forth herein, Plaintiff RUBY CAVEECK is entitled to recover for her personal injuries; past, present, and future medical and related expenses; past, present, and future lost wages; past, present and

future loss of earning capacity; and past, present and future mental and physical pain and suffering, and Plaintiff should be awarded punitive damages.

Plaintiff demands trial by jury, judgment against Defendants, jointly and severally, for compensatory and punitive damages in an amount not less than $75,001, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment of the U.S. Constitution.

Respectfully Submitted,

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